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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/580,463	05/26/2000	Carl J. Wheeler	VICAL1100-I	2067
26111	7590	07/25/2002	EXAMINER	
STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W., SUITE 600 WASHINGTON, DC 20005-3934			SCHNIZER, RICHARD A	
ART UNIT		PAPER NUMBER		
1635		14		
DATE MAILED: 07/25/2002				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/580,463	WHEELER, CARL J.
	Examiner Richard Schnizer	Art Unit 1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 19 April 2002.
- 2a) This action is **FINAL**.                                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 47-94 is/are pending in the application.
- 4a) Of the above claim(s) 50-67, 71-73, 77-85 and 87-92 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 47-49, 68-70, 74-76, 86, 93 and 94 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4 &amp; 5</u>	6) <input type="checkbox"/> Other: _____

Art Unit: 1632

### **DETAILED ACTION**

An amendment was received and entered as Paper No. 10 on 4/19/02. Applicant's election without traverse of group I, claims 47-94, drawn to compositions comprising a cationic lipid, and methods of delivering a biologically active agent to an animal cell is acknowledged. Applicant's election of the species of R<sub>9</sub> wherein R<sub>9</sub> comprises NR<sub>12</sub>-C(O)-NR<sub>13</sub>-R<sub>16</sub>-NR<sub>14</sub>-C(O)-NR<sub>15</sub> is acknowledged. Claims 47, 48, 68-70, 74-86, 93, and 94 read on this species. A search of the prior art indicated that this species was novel and non-obvious. In accordance with MPEP 603.02, the search was extended to include C<sub>1</sub>-C<sub>10</sub> substituted alkyl groups. See rejections under 35 USC 102, below. This species reads on claims 47-49 and 76-86. Claims 47-49, 68-70, 74-~~76~~, 93, and 94, and the species of R<sub>9</sub> = NR<sub>12</sub>-C(O)-NR<sub>13</sub>-R<sub>16</sub>-NR<sub>14</sub>-C(O)-NR<sub>15</sub> and R<sub>9</sub> = C<sub>1</sub>-C<sub>10</sub> substituted alkyl groups are under consideration in this Office Action.

The scope of claims 47-49 and 76-86 that embraces a method of delivering a biologically active agent to a plant cell will not be considered, there being no allowable generic or linking claim.

#### ***Claim Objections***

Claim 82 and dependents are objected to because they recite non-elected subject matter. As noted above, Applicant has elected methods of delivering a biologically active agent to an

Art Unit: 1632

animal cell. However, claims 82 and dependents recite methods of delivering a biologically active agent to a plant cell. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 47-49, 68-70, 74-76 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 47-49, 68-70, 74-76 were amended in Paper No. 8 to include the proviso: "provided that R<sub>9</sub> is not C<sub>3</sub> to C<sub>22</sub> unsubstituted alkyl." Applicant asserts that this amendment is supported in the specification at pages 6 and 7; pages 9-12; pages 28-30; and pages 36-39. However, Applicant has failed to point to any literal support for this limitation, and none is apparent in the specification, so it constitutes new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1632

Claims are 47-49, 68-70, 74-86, 93, and 94 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 47-49, 68-70, 74-86, 93, and 94 are indefinite because the metes and bounds of “non-toxic anions” is unclear. The specification fails to define this term, and there is no single art-recognized definition. Any anion could be non-toxic if present in small enough amounts, just as any anion could be considered toxic if present in high enough amounts. Furthermore, it is unclear what is intended by “toxic”. Does toxic refer to the effect on individual cells in an organism, or on the organism as a whole? Would an anion, present in sufficient concentration to cause limited cell death with no apparent overall effect on the organism, be considered to be toxic?

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 47-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Spadini et al (US Patent 3,983,079).

Art Unit: 1632

Spadini teaches a composition according to the structure recited in instant claims 47 and 48, wherein R9 is the substituted alkyl group  $\text{CH}_2\text{-CHOH-CH}_2$ . See e.g. column 3, lines 60-65. Thus Spadini anticipates the claims.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 83 is rejected under 35 U.S.C. 103(a) as being unpatentable over Spadini et al (US Patent 3,983,079).

Spadini teaches a composition according to the structure recited in instant claim 83, wherein R9 is the substituted alkyl group  $\text{CH}_2\text{-CHOH-CH}_2$ . See e.g. column 3, lines 60-65.

Spadini fails to teach a kit or a container comprising the composition, but it would have been obvious to one of ordinary skill in the art at the time the invention was made to place the composition of Spadini into a container in order to store it, such procedures being routine in the art. It is noted that although Spadini fails to teach a polynucleotide and means for administering the composition to a vertebrate, these limitations are optional and need not be taught.

Thus the invention as a whole was *prima facie* obvious.

Art Unit: 1632

***Conclusion***

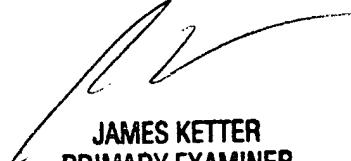
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 703-306-5441. The examiner can normally be reached Monday through Friday between the hours of 6:20 AM and 3:50 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Leguyader, can be reached at 703-308-0447. The FAX numbers for art unit 1632 are 703-308-4242, and 703-305-3014. Additionally correspondence can be transmitted to the following RIGHTFAX numbers: 703-872-9306 for correspondence before final rejection, and 703-872-9307 for correspondence after final rejection.

Inquiries of a general nature or relating to the status of the application should be directed to the Patent Analyst Trina Turner whose telephone number is 703-305-3413.

Richard Schnizer, Ph.D.



JAMES KETTER  
PRIMARY EXAMINER